



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment

##### Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-0361.

#### **Project: Notification of Intent to Use Schedule III, IV, or V Controlled Medications for the Treatment of Opioid Use Disorder Under 21 U.S.C. 823(g)(2) (OMB No. 0930-0234 and OMB No. 0930-0369) – Revision**

The Drug Addiction Treatment Act of 2000 (“DATA,” Pub. L. 106–310) amended the Controlled Substances Act (21 U.S.C. 823(g)(2)) to permit qualifying practitioners to seek and obtain waivers to prescribe certain approved controlled medications for the treatment of opioid use disorder. The legislation set eligibility and certification requirements as well as an interagency notification review process for practitioners who seek waivers. To implement these provisions, SAMHSA developed Notification of Intent Forms that facilitate the submission and review of notifications. The forms provide the information necessary to determine whether practitioners meet the qualifications for waivers set forth under the law at the 30-, 100-, and 275-patient limits. This includes the annual reporting requirements for practitioners with waivers for a 275-patient limit. On October 24, 2018, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Public Law 115-71) was signed into law. Sections 3201 – 3202 of the SUPPORT Act made several amendments to the Controlled Substances Act regarding office-based opioid use disorder treatment that affords practitioners greater flexibility in the provision of Medications for Opioid Use Disorder (MOUD).

The SUPPORT Act expands the definition of “qualifying other practitioner” enabling Clinical Nurse Specialists, Certified Registered Nurse Anesthetists, and Certified Nurse Midwives (CNSs, CRNAs, and CNMs) to apply for a Drug Addiction Treatment Act of 2000 (DATA) waiver until October 1, 2023. It also allows qualified practitioners (i.e., MDs, DOs, NPs, PAs, CNSs, CRNAs, and CNMs) who are board certified in addiction medicine or addiction psychiatry, -or- practitioners who provide MOUD in a qualified practice setting, to start treating up to 100 patients in the first year of practice (as defined in 42 CFR 8.2) with a waiver.

Further, the SUPPORT Act extends the ability to treat up to 275 patients to “qualifying other practitioners” (i.e., NPs, PAs, CNSs, CRNAs, and CNMs) if they have a waiver to treat up to 100 patients for at least one year and provide treatment of Opioid Use Disorder with covered medications (as such terms are defined under 42 CFR 8.2) in a qualified practice setting as described under 42 CFR 8.615. Finally, the SUPPORT Act also expands how physicians could qualify for a waiver. Under the statute now, physicians can qualify for a waiver if they have received at least 8 hours of training on treating and managing patients with opioid use disorder, as listed in the statute if the physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician submits a Notice of Intent to SAMHSA. In order to expedite the new provisions of the SUPPORT Act, SAMHSA sought and received a Public Health Emergency Paperwork Reduction Act Waiver.

On April 28, 2021 the Department of Health and Human Services (HHS) issued the new Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder (86 FR 22439) in an expedited manner. The Practice Guidelines allow practitioners who wish to obtain a 30-patient waiver to forego the 8-hour training requirement for physicians and 24-hour training for other qualifying practitioners. Practitioners utilizing this training exemption are limited to treating no more than 30-patients at a time and time spent practicing under this exemption will not qualify the practitioner to qualify for a higher patient level. In addition, the new Practice

Guidelines removed the requirement to provide counseling and other ancillary services (i.e., psychosocial services).

The collection of information within the application is essential to the implementation of SAMHSA’s mission to reduce the impact of substance use disorders on America's communities. Practitioners may use these forms for various types of notifications: (a) New Notification to treat up to 30 patients; (b) New Notification, with the intent to immediately facilitate treatment of an individual (one) patient; (c) Second notification of need and intent to treat up to 100 patients; (d) New notification to treat up to 100 patients, and (e) New notification to treat up to 275 patients. Under “new” notifications, practitioners make their initial waiver requests to SAMHSA.

“Immediate” notifications inform SAMHSA and the Attorney General of a practitioner’s intent to prescribe immediately to facilitate the treatment of an individual (one) patient under 21 U.S.C. 823(g)(2)(E)(ii). The form collects data on the following items: Practitioner name; state medical license number; medical specialty; and DEA registration number; address of primary practice location, telephone and fax numbers; e-mail address; name and address of group practice; group practice employer identification number; names and DEA registration numbers of group practitioners; purpose of notification: new, immediate, or renewal; certification of qualifying criteria for treatment and management of patients with opioid use disorder; certification of capacity to provide directly or refer patients for appropriate counseling and other appropriate ancillary services; certification of maximum patient load, certification to use only those medication formulations that meet the criteria in the law. The form also notifies practitioners of Privacy Act considerations and permits practitioners to expressly consent to disclose limited information to the SAMHSA Buprenorphine Physician and Behavioral Health Treatment Services locators. The following table summarizes the estimated annual burden for the use of these forms.

42 CFR Citation	Purpose of Submission	Estimated Number of respondents	Responses/ Respondent	Burden/ Response (Hr.)	Total Burden (Hrs.)
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	Notification of Intent	1,800	1	0.083	149
	Notification to Prescribe Immediately	60	1	0.083	5
	Notice to Treat up to 100 patients	600	1	0.04	24
	Notice to Treat up to 275 patients	960	1	0.081	78
	<b>Subtotal</b>	<b>3,420</b>	<b>-</b>	<b>-</b>	<b>256</b>
<b>Burden Associated with the Final Rule That Increased the Patient Limit</b>					
8.620 (a)-(c)	Request for Patient Limit Increase*	620	1	0.5	310
	Request for Patient Limit Increase*	620	1	0.5	310
	Request for Patient Limit Increase*	620	1	0.5	310
8.64	Renewal Request for a Patient Limit Increase*	312	1	0.5	156
	Renewal Request for a Patient Limit Increase*	312	1	0.5	156
	Renewal Request for a Patient Limit Increase*	312	1	0.5	156
8.655	Request for a Temporary Patient Increase for an Emergency*	12	1	3	36
	Request for a Temporary Patient Increase for an Emergency*	12	1	3	36
	Request for a Temporary Patient Increase for an Emergency*	12	1	3	36
	<b>Subtotal</b>	<b>2,497</b>	<b>-</b>	<b>-</b>	<b>1,279</b>
<b>Burden Associated with the Final Rule That Outlined the Reporting Requirements</b>					
8.635	Practitioner Reporting Form*	1,620		3	4860
	“Qualifying Other Practitioner” under 21 USC § 823(g)(2) – Nurse Practitioners	979	1	0.066	65
	“Qualifying Other Practitioner” under 21 USC § 823(g)(2) – Physician Assistants	708	1	0.066	47
	“Qualifying Other Practitioner” under 21 USC § 823(g)(2) – Certified Nurse Specialists	708	1	0.066	47
	“Qualifying Other Practitioner” under 21 USC § 823(g)(2) – Certified Nurse Mid-Wives	708	1	0.066	47
	“Qualifying Other Practitioner” under 21 USC § 823(g)(2) – Certified Registered Nurse Anesthetists	708	1	0.066	47
	<b>Sub Total</b>	<b>5,431</b>	<b>1</b>	<b>-</b>	<b>5112</b>
	<b>Total Burden</b>	<b>6,561</b>		<b>-</b>	<b>6,647</b>

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

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